

U.S. Department of Justice



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SOUTHERN DIVISION
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Southern Division*

*Civil Division
Consumer Protection Branch*

AT BALTIMORE
 CLERK U.S. DISTRICT COURT
 SOUTHERN DIVISION
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January 2, 2013

Geoffrey R. Garinther, Esq.
 W. Warren Hamel, Esq.
 Winifred M. Weitsen, Esq.
 Venable LLP
 750 E. Pratt Street
 Suite 900
 Baltimore, Maryland 21202

Re: United States v. Ranbaxy USA, Inc.,
Crim. No. [to be determined] JFM-13-0238

Dear Mr. Garinther, Mr. Hamel and Ms. Weitsen:

This letter, together with the Sealed Supplement, confirms the plea agreement that has been offered to the Defendant by the United States Attorney's Office for the District of Maryland and the Consumer Protection Branch of the U.S. Department of Justice (collectively "this Office"). **The agreement will be presented to the Court pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C).** This agreement is contingent upon execution of a Civil Settlement Agreement between Ranbaxy USA, Inc. and the United States. If the Defendant accepts this offer, please have a responsible corporate officer execute it in the spaces provided below. The terms of the agreement are as follows:

Offenses of Conviction

1. The Defendant agrees to knowingly and voluntarily waive indictment and plead guilty to Counts One through Seven of a criminal information to be filed against it, which will charge it with introduction into interstate commerce of adulterated drugs, with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 351(a)(2)(B); failure to timely file required reports with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(e) and 333(a)(2);

false statements, in violation of 18 U.S.C. § 1001; and aiding and abetting, in violation of 18 U.S.C. § 2. The Defendant admits that it is, in fact, guilty of these offenses and will so advise the Court.

Elements of the Offenses

2. The elements of the offenses to which the Defendant has agreed to plead guilty, and which this Office would prove if the case went to trial, are as follows:

Count One (Introduction into Interstate Commerce of Adulterated Drugs): (1) the Defendant introduced or caused the introduction of a drug; (2) the drug was adulterated; (3) the Defendant acted knowingly; (4) the drug was introduced into interstate commerce; and (5) the Defendant did so with the intent to defraud or mislead.

Counts Two and Three (Failure to Timely File Required Reports): (1) the Defendant was a manufacturer of a drug approved by the FDA pursuant to an Abbreviated New Drug Application; (2) the Defendant was aware of the failure of one or more distributed batches of a drug product to meet the specification established for it under the drug's ANDA; (3) the Defendant failed to submit a "field alert report" within three working days after receiving any information concerning such failure; and (4) the Defendant did so with the intent to defraud or mislead.

Counts Four through Seven (False Statements): (1) the Defendant made and/or aided and abetted the making of a statement or representation; (2) the statement or representation was within the jurisdiction of the Executive Branch of the United States government, specifically the Food and Drug Administration; (3) the statement or representation was false; (4) the false statement or representation was made knowingly and willfully; and (5) the statement or representation was material.

For each offense, the Defendant is guilty as an aider and abettor if the Defendant (1) willfully and knowingly associated itself in some way with the crime, and (2) willfully and knowingly sought by some act to help make the crime succeed.

Penalties

3. The maximum sentence provided by statute for each offense to which the Defendant is pleading guilty is as follows: a fine of \$500,000, or an amount not more than the greater of twice the gross gain or twice the gross loss relating to the offense, pursuant to 18 U.S.C. § 3571(d), and a term of at least one year but not more than five years of probation, pursuant to 18 U.S.C. § 3561(c)(1). On the basis of Defendant's gross gain of not less than \$100,000,000 for the sale of drugs described in the criminal information and Attachment A, the maximum possible fine is \$200,000,000. In addition, the Defendant must pay \$2,800 (\$400 per count) as a special assessment pursuant to 18 U.S.C. § 3013, which will be due and should be paid at or before the time of sentencing. This Court may also order it to make restitution pursuant to 18 U.S.C. §§ 3663,

3663A, and 3664.¹ If a fine or restitution is imposed, it shall be payable immediately, unless, pursuant to 18 U.S.C. § 3572(d), the Court orders otherwise.

Waiver of Rights

4. The Defendant understands that by entering into this agreement, it surrenders certain rights as outlined below:

a. If the Defendant had entered pleas of not guilty, it would have had the opportunity to assert the right to a speedy jury trial with the close assistance of competent counsel. That trial could be conducted by a judge, without a jury, if the Defendant, this Office, and the Court all agreed.

b. If the Defendant elected and were granted a jury trial, the jury would be composed of twelve individuals selected from the community. Counsel and the Defendant would have the opportunity to challenge prospective jurors who demonstrated bias or who were otherwise unqualified, and would have the opportunity to strike a certain number of jurors peremptorily. All twelve jurors would have to agree unanimously before the Defendant could be found guilty of any count. The jury would be instructed that the Defendant was presumed to be innocent, and that presumption could be overcome only by proof beyond a reasonable doubt.

c. If the Defendant went to trial, the government would have the burden of proving the Defendant guilty beyond a reasonable doubt. The Defendant would have the right to confront and cross-examine the government's witnesses. The Defendant would not have to present any defense witnesses or evidence whatsoever. If the Defendant wanted to call witnesses in its defense, however, it would have the subpoena power of the Court to compel the witnesses to attend.

d. The Defendant would have the right to call witnesses to testify in its own defense if it so chose, and it would have the right to refuse to call witnesses to testify. If it chose not to call witnesses to testify, the Court could instruct the jury that they could not draw any adverse inference from its decision not to call witnesses to testify.

e. If the Defendant were found guilty after a trial, it would have the right to appeal the verdict and the Court's pretrial and trial decisions on the admissibility of evidence to see if any errors were committed which would require a new trial or dismissal of the charges against it. By pleading guilty, the Defendant knowingly gives up the right to appeal the verdict and the Court's decisions.

¹ Pursuant to 18 U.S.C. § 3612, if the Court imposes a fine in excess of \$2,500 that remains unpaid 30 days after it is imposed, the Defendant shall be charged interest on that fine, unless the Court modifies the interest payment in accordance with 18 U.S.C. § 3612(f)(3).

f. By pleading guilty, the Defendant will be giving up all of these rights, except the right, under the limited circumstances set forth in the "Waiver of Appeal" paragraph below, to appeal the sentence. By pleading guilty, the Defendant understands that its counsel and designated representative may have to answer the Court's questions both about the rights it is giving up and about the facts of the case. Any statements the Defendant's counsel and representative make during such a hearing would not be admissible against it during a trial except in a criminal proceeding for perjury or false statement.

g. If the Court accepts the Defendant's pleas of guilty, there will be no further trial or proceeding of any kind, and the Court will find it guilty.

Advisory Sentencing Guidelines Apply

5. The Defendant understands that the Court will determine a sentencing guidelines range for this case (henceforth the "advisory guidelines range") pursuant to the Sentencing Reform Act of 1984 at 18 U.S.C. §§ 3551 through 3742 (excepting 18 U.S.C. §§ 3553(b)(1) and 3742(e)) and 28 U.S.C. §§ 991 through 998. The Defendant further understands that the Court will impose a sentence pursuant to the Sentencing Reform Act, as excised, and must take into account the advisory guidelines range in establishing a reasonable sentence.

Factual and Advisory Guidelines Stipulation

6. This Office and the Defendant understand, agree, and stipulate to the Statement of Facts set forth in Attachment A hereto which this Office would prove beyond a reasonable doubt, and to the following sentencing guidelines factors:

- a. The base fine is \$100 million, which is the pecuniary gain to the organization from the offenses. *See U.S.S.G. § 8C2.4(a)(2).*
- b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is **6**, which is determined as follows:
 - i. Base culpability score is **5** pursuant to U.S.S.G. § 8C2.5(a);
 - ii. **1** point is added pursuant to U.S.S.G. § 8C2.5(b)(5), in that the organization had 10 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offenses.
- c. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of **6** is 1.20 - 2.40.
- d. Pursuant to U.S.S.G. § 8C2.7, the advisory Guideline Fine Range is \$120,000,000 to \$240,000,000.

7. This Office and the Defendant agree that with respect to the calculation of the advisory guidelines range, no other offense characteristics, sentencing guidelines factors, potential departures or adjustments set forth in the United States Sentencing Guidelines will be raised or are in dispute.

Agreed Disposition

8. The parties stipulate and agree pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) that the following sentence is the appropriate disposition of this case:

- a. a fine of \$130,000,000, payable in full before the fifteenth day after the date of judgment.
- b. a criminal forfeiture money judgment of \$20,000,000, also payable in full before the fifteenth day after the date of judgment.
- c. a special assessment of \$2,800.
- d. The above-referenced agreed-upon sentence is contingent upon the execution of a Civil Settlement Agreement between Ranbaxy USA, Inc. and the United States, which is being signed contemporaneously with this Plea Agreement and is appended as Attachment B, and which requires the payment of \$350,000,000, plus interest.
- e. In light of the Civil Settlement Agreement and the pending civil action, *United States of America ex rel. Dinesh S. Thakur v. Ranbaxy USA, Inc., et al.*, Civil Action No. JFM-07-962 (D. Md.), the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. See 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, this Office agrees that it will not seek a separate restitution order as to the Defendant as part of the resolution of the Information and the parties agree that the appropriate disposition of this case does not include a restitution order.
- f. This agreement does not affect the Court's discretion to impose any lawful term of probation or to set any lawful conditions of probation. In the event that the Court rejects this plea agreement, either party may elect to declare the agreement null and void. Should the Defendant so elect, it will be afforded the opportunity to withdraw its plea pursuant to the provisions of Federal Rule of Criminal Procedure 11(c)(5).
- g. This Office and the Defendant jointly submit that this Plea Agreement, together with the record that will be created by this Office and the Defendant at the plea and

sentencing hearings, will provide sufficient information concerning the Defendant, the crimes charged in this case, and the Defendant's role in the crimes to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. This Office and the Defendant agree to request jointly that the Court accept the Defendant's guilty pleas and impose sentence on an expedited schedule as early as the date of arraignment, based upon the record provided by the Defendant and this Office, under the provisions of Fed. R. Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1. The Court's denial of the request to impose sentence on an expedited schedule will not void this Plea Agreement.

Forfeiture

9. The Defendant understands that the court will, upon acceptance of its guilty plea, enter an order of forfeiture as part of its sentence, and that the order of forfeiture may include assets directly traceable to its offense, substitute assets and/or a money judgment equal to the value of the property derived from, or otherwise involved in, the offense. Specifically, the Court will order the forfeiture of a money judgment of \$20 million, equivalent to quantities of drugs which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and/or 351(a)(2)(b), namely the specified drugs introduced during the specified period identified in the Information. The Defendant agrees to consent to the entry of orders of forfeiture for such property and waives the requirements of Federal Rules of Criminal Procedure 11(b)(1)(J), 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, advice regarding the forfeiture at the change-of-plea hearing, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment.

Assisting the Government with Regard to the Forfeiture

10. The Defendant agrees to assist fully in the forfeiture of the foregoing assets. The Defendant agrees to disclose all of its assets and sources of income to the United States, and to take all steps necessary to pass clear title to the forfeited assets to the United States, including but not limited to executing any and all documents necessary to transfer such title, assisting in bringing any assets located outside of the United States within the jurisdiction of the United States, and taking whatever steps are necessary to ensure that assets subject to forfeiture are not sold, disbursed, wasted, hidden or otherwise made unavailable for forfeiture. The Defendant further agrees that it will not assist any third party in asserting a claim to the forfeited assets in an ancillary proceeding and that its representatives will testify truthfully in any such proceeding.

Waiver of Further Review of Forfeiture

11. The Defendant further agrees to waive all constitutional, legal and equitable challenges (including direct appeal, habeas corpus, or any other means) to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. The Defendant also agrees not to challenge or seek review of any civil or administrative forfeiture of any property subject to forfeiture under this agreement, and will not assist any third party with regard to such challenge or review or with regard to the filing of a petition

for remission of forfeiture.

Agreement Not to Further Prosecute Other Offenses the Defendant May Have Committed

12. a. Pursuant to Fed. R. Crim. P. 11(c)(1)(A), this Office agrees that, other than the charges in the Information described in Paragraph 1, it shall not further prosecute the Defendant and/or the related corporate entities collectively referred to as Ranbaxy in Attachment A for any additional federal criminal or forfeiture charges or charges under the Food Drug and Cosmetic Act with respect to the conduct that falls within the scope of the Information to which the Defendant is pleading guilty, was the subject of the grand jury investigation in the District of Maryland, or was known to this Office prior to the date of this Agreement relating to:

i. the production, manufacturing, processing, packing and/or holding of drugs at the manufacturing facilities at Paonta Sahib and Dewas ("Paonta Sahib and Dewas facilities") between the years 2003 and 2010; or

ii. conduct, actions, omissions, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and/or actions regarding the Paonta Sahib and Dewas facilities between the years 2003 and 2010.

b. This Office does not decline criminal prosecution of the Defendant for any other conduct beyond that set forth above.

c. This declination is expressly contingent upon:

i. the guilty plea of the Defendant to the Information being accepted by the Court and not withdrawn or otherwise challenged; and

ii. the Defendant's performance of all of its obligations as set forth in this Agreement and the Civil Settlement Agreement.

d. If the Defendant's guilty plea is not accepted by the Court or is withdrawn for any reason, or the Defendant should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void. This Office expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of the Defendant, in connection with the conduct encompassed by this plea agreement, within the scope of the investigation, or known to this Office.

Waiver of Statute of Limitations

13. The Defendant understands and agrees that, pursuant to tolling agreements executed by the parties, the charges set forth in the Information are not time-barred by the statute of limitations. The Defendant explicitly waives all defenses based on the statute of limitations with

respect to any prosecution that is not time-barred on the date this plea agreement is signed. The Defendant understands and agrees that should the convictions following its pleas of guilty pursuant to this agreement be vacated for any reason, then any prosecution that is not time-barred as of the date of the signing of this agreement may be commenced or reinstated against the Defendant, notwithstanding the expiration of the statute of limitations between the signing of this agreement and the commencement or reinstatement of such prosecution.

Waiver of Appeal

14. In exchange for the concessions made by this Office and the Defendant in this plea agreement, if the Court accepts this agreement and imposes the agreed-upon sentence, this Office and the Defendant waive their rights to appeal as follows:

a. The Defendant knowingly waives all right, pursuant to 28 U.S.C. § 1291 or otherwise, to appeal the Defendant's conviction.

b. If the Court accepts the agreed-upon sentence, the Defendant and this Office knowingly waive all right, pursuant to 18 U.S.C. § 3742 or otherwise, to appeal whatever sentence is imposed (including the right to appeal any issues that relate to the establishment of the advisory guidelines range, the weighing of the sentencing factors, and the decision whether to impose and the calculation of any fine, order of forfeiture, order of restitution, and term or condition of probation).

c. Nothing in this agreement shall be construed to prevent the Defendant or this Office from invoking the provisions of Federal Rule of Criminal Procedure 35(a), or from appealing from any decision thereunder, should a sentence be imposed that resulted from arithmetical, technical, or other clear error.

d. The Defendant waives any and all rights under the Freedom of Information Act relating to the investigation and prosecution of the above-captioned matter and agrees not to file any request for documents from this Office or any investigating agency.

Obstruction or Other Violations of Law

15. The Defendant agrees that it will not commit any offense in violation of federal, state or local law between the date of this agreement and its sentencing in this case. In the event that the Defendant (i) engages in conduct after the date of this agreement which would justify a finding of obstruction of justice under U.S.S.G. § 3C1.1, or (ii) fails to accept personal responsibility for its conduct by failing to acknowledge its guilt to the probation officer who prepares the Presentence Report, or (iii) commits any offense in violation of federal, state or local law, then this Office will be relieved of its obligations to the Defendant as reflected in this agreement. Specifically, this Office will be free to argue sentencing guidelines factors other than those stipulated in this agreement, and it will also be free to make sentencing recommendations other than those set out in this agreement. As with any alleged breach of this agreement, this Office will

bear the burden of convincing the Court of the Defendant's obstructive or unlawful behavior and/or failure to acknowledge personal responsibility by a preponderance of the evidence. The Defendant acknowledges that it may not withdraw its guilty plea because this Office is relieved of its obligations under the agreement pursuant to this paragraph.

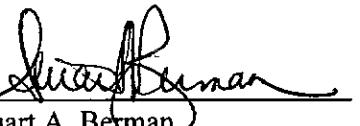
Entire Agreement

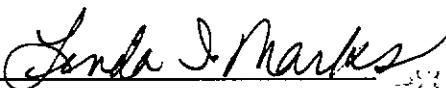
16. This letter supersedes any prior understandings, promises, or conditions between this Office and the Defendant and, together with the Sealed Supplement, constitutes the complete plea agreement in this case. The Defendant acknowledges that there are no other agreements, promises, undertakings or understandings between the Defendant and this Office other than those referred to or set forth in this letter and the Sealed Supplement and none will be entered into unless in writing and signed by all parties.

If the Defendant fully accepts each and every term and condition of this agreement, please sign and have the Defendant sign the original and return it to me promptly.

Very truly yours,

Rod J. Rosenstein
United States Attorney

By: 
Stuart A. Berman
Assistant United States Attorney

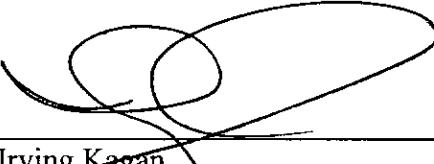
By: 
Linda I. Marks
Senior Litigation Counsel

By: 
Perham Gorji
Trial Attorney

U.S. Department of Justice
Consumer Protection Branch

By virtue of a Resolution Adopted by the Board of Directors of Ranbaxy USA, Inc. (appended to this agreement as Attachment C), I have been authorized, empowered and directed to represent Ranbaxy USA, Inc. before the Court in order to make statements and confirmations in accordance with this agreement, including entering a guilty plea on behalf of the Defendant. I have read this agreement, including the Sealed Supplement, and carefully reviewed every part of it with the attorneys for Ranbaxy USA, Inc. I understand it, and I voluntarily agree to it. Specifically, I have reviewed the Factual and Advisory Guidelines Stipulation with the attorneys, and I do not wish to change any part of it. Ranbaxy USA, Inc. is completely satisfied with the representation of its attorneys.

3/1/13
Date



Irving Kagan
Corporate Secretary
Ranbaxy USA, Inc.

We are the attorneys for Ranbaxy USA, Inc. We have carefully reviewed every part of this agreement, including the Sealed Supplement, with the Defendant and its designated representative. The Defendant has advised us that it understands and accepts its terms. To our knowledge, its decision to enter into this agreement is an informed and voluntary one.

March 1, 2013
Date



W. Warren Hamel, Esq.
Geoffrey R. Garinther, Esq.
Winifred M. Weitsen, Esq.